DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 74-98, drawn to immunodiagnosis method.

Group II, claims 99-104, drawn to method of making/designing pathogen peptide compositions.

Group III, claim 105, drawn to virus or bacteria peptide compositions having sequences.

Group IV, claims 106-126 and 128-137, drawn to peptide sequence compositions for detecting T-lymphocyte activation and immunodiagnosis of disease.

Group V, claims 127, drawn to immunostimulant compositions used for immunodiagnosis of enteric infections.

Group VI, claims 138-145, drawn to kit comprising peptide compositions and protein/antigen lysates for use in immunodiagnosis of organ-specific infections.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I is a method of immunodiagnosing diseases using antigen compositions which may be in the form of raw protein extract, purified protein, recombinant protein or synthetic peptides that are specific to T-lymphocyte activation that provides indication of pathogenic disease or vaccination; Group II is a method of designing peptides from pathogenic proteins by defining binding to HLA Class I, identifying immunodominant regions which bind to two or three different HLA loci, and selecting peptides of at least 9 amino acid length overlapping the immunodominant region- the peptides made by the method of Group II are not required in Group I; Group III is a composition of peptides which include Ortho-

Poxvirus peptides, Anthrax peptides, and SARS Coronavirus peptides- the specific peptides defined by sequences in Group III are not required in Group I or Group II; Group IV is a composition of peptides identified by amino acid sequences for detecting specific T-lymphocyte activation to provide indication of infections, and which are within any one of peptides from SEQ ID No. 1 to SEQ ID No. 182- the specific peptides defined by sequences in Group IV which provide indication of diseases include HIV and CMV are not required in Groups I-III; Group V is an immunostimulant composition comprising bacterial or viral proteins or antigens that provide indication of enteric infections; the bacterial or viral proteins in Group V are not required in Groups I-IV; Group VI is a kit comprising reagents and compositions for detecting T-lymphocyte activation using peptides derived from purified proteins or antigens of bacteria or virus which provide organ-specific infections including sexually transmitted disease, in utero infections, post-transplant infections, and blood-borne infections; the purified proteins from which peptides are derived for use in immunodiagnosing these diseases are not required in Groups I-V.

Therefore, the inventions of Groups I-VI do not form a general inventive concept, as they do not share a common special technical feature. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I,

Species Group A: species claims 87-98

Species a) - infectious agents: claims 91-92

Species b) - tumor antigens: claims 93-94

Species c) – autoimmune antigens: claims 95-96

Species d) – allergens.

Species Group B: claim 90

Species – stimulus preparation select one from:

SEQ ID No. 1 … to … SEQ ID No. 182, select in accordance to T-lymphocyte specific agent corresponding to disease elected from Group I, Species A)-D).

Group II: method to prepare species composition from a pathogen: claims 100-102

Species A) – Variola pathogen: claims 100, 101

Species B) – Anthrax pathogen: claims 100, 102

Species C) – Plague pathogen: claims 100, 102

Species D) – Tularemia pathogen: claims 100, 102

Species E) – SARS pathogen: claims 100, 101.

Group III: composition of peptide species: claim 105:

Species A) – Ortho-Poxvirus peptides:

Subspecies: SEQ ID No. 84-85

SEQ ID No. 86-87

SEQ ID No. 88-90

SEQ ID No. 91-92

SEQ ID No. 93

SEQ ID No. 94-95

SEQ ID No. 96-97

SEQ ID No. 98-99

SEQ ID No. 100-101

SEQ ID No. 102-103

Species B) – Anthrax peptides:

Subspecies: SEQ ID No. 74-83

Species C) – SARS peptides:

Subspecies: SEQ ID No. 44-59

SEQ ID No. 45-46, 60-61

SEQ ID No. 47-48, 62-63

SEQ ID No. 49-58, 64-73

SEQ ID No. 45-46

SEQ ID No. 173-177

Group IV: composition species for detecting T-lymphocyte activation immunodiagnostic of infections: claims 106-126 and 128-137

Species A) – HIV infection: claims 107-108

Subspecies – peptides select one from:

SEQ ID No. 1 … to … SEQ ID No. 20, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species B) – CMV infection: claims 109-110

Subspecies – peptides select one from:

SEQ ID No. 21 … to … SEQ ID No. 43, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species C) – SARS coronavirus infection: claims 111-119

Subspecies – peptides select one from:

SEQ ID No. 44 … to … SEQ ID No. 73, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

SARS Subspecies – peptides select one from:

c1) SARS E-protein- SEQ ID No. 44

SEQ ID No. 59,

c2) SARS M-protein- SEQ ID No. 45

SEQ ID No. 46

SEQ ID No. 60

SEQ ID No. 61,

c3) SARS N-protein- SEQ ID No. 47

SEQ ID No. 48

SEQ ID No. 62

SEQ ID No. 63,

c4) SARS S-protein- SEQ ID No. 49 … to … SEQ ID No. 58

SEQ ID No. 64 … to ... SEQ NI No. 73,

c5) A-SARS - SEQ ID No. 44 … to … SEQ ID No. 58

c6) B-SARS - SEQ ID No. 59 … to … SEQ ID No. 73.

Species D) – B. anthracis infection: claims 122-123

Subspecies – peptides select one from:

SEQ ID No. 74 … to … SEQ ID No. 83, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species E) – Orthopox viridae infection: claims 124-125

Subspecies – peptides select one from:

SEQ ID No. 84 … to … SEQ ID No. 103, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species F) – threat disease infection: claim 126

Subspecies – peptides select one from:

SEQ ID No. 74 … to … SEQ ID No. 83, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

SEQ ID No. 84 … to … SEQ ID No. 103, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species G) – alpha-fetoprotein specific T-lymphocyte activation: claims 128-129

SEQ ID No. 104 … to … SEQ ID No. 122, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species H) – PSA specific T-lymphocyte activation: claims 130-131

SEQ ID No. 123 … to … SEQ ID No. 142, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species I) – MAGE-3 specific T-lymphocyte activation: claim 132-133

SEQ ID No. 104 … to … SEQ ID No. 122, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species J) – NY-ESO-1 antigen specific T-lymphocyte activation: claims 134-135

SEQ ID No. 158 … to … SEQ ID No. 172, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Species K) –tumors: claims 136-137

SEQ ID No. 104 … to … SEQ ID No. 122, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

SEQ ID No. 123 … to … SEQ ID No. 142, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

SEQ ID No. 143 … to … SEQ ID No. 157, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

SEQ ID No. 158 … to … SEQ ID No. 172, select in accordance to immunodiagnosis of corresponding selected disease elected from Group IV, Species A)-K).

Group V: immunostimulant composition species for enteric infections claim 127.

Species A) – Shigella groups A, A1, B, C, C1, C2 antigens

Species B) – Salmonella groups A, O antigens

Species C) – Enterovirus 70 antigen lysate

Species D) – HAV antigen lysate

Species E) – HEV Hepatitis E Virus ORF2 antigen

Species F) – Helicobacter pylori HPSa antigen

Species G) – Clostridium difficile Toxin A antigen.

Group VI:

Species Group A: claim 138

Species – stimulus preparation select one from:

SEQ ID No. 1 … to … SEQ ID No. 182, select in accordance to corresponding disease elected from Group VI, Species Group B, subspecies a)-g).

Species Group B: protein or antigen lysate- claims 139-145

Species a) – Respiratory infections: claim 139

Subspecies: Influenza A virus H3N2 antigen

Influenza A virus H1N1 antigen

Influenza B virus Hong Kong

Influenza B virus Victoria

Influenza B virus Tokio

Influenza B virus Qiengdao

Influenza B virus Lee

Parainfluenza virus, Group I

Parainfluenza virus, Group II

Parainfluenza virus, Group II

Parainfluenza virus, Group IV

Respiratory Syncytial Virus RSV

SARS coronavirus recombinant protein E

SARS coronavirus recombinant protein M

SARS coronavirus recombinant protein

Nucleocapsid aa. 1-49

SARS coronavirus recombinant protein

Nucleocapsid aa. 192-220

echovirus

Coxsackie B6 antigen

Coxsackie A9 antigen

Coxsackie A16 antigen

Adenovirus Type 3

Adenovirus Type 6

Adenovirus Type 21

Legionella pneumophilia antigen

Mycoplasma pneumoniae antigen

Chlamydia pneumoniae antigen.

Species b) – Enteric infections: claim 140

Subspecies: Shigella groups A, A1, B, C, C1, C2 antigens

Salmonella groups A, O antigens

Enterovirus 70 antigen lysate

HAV antigen lysate

HEV Hepatitis E Virus ORF2 antigen

Helicobacter pylori HPSa antigen

Clostridium difficile Toxin A antigen.

Species c) – sexually transmitted disease: claim 141

Subspecies: Treponema pallidum p15 recombinant antigen

Treponema pallidum p17 recombinant antigen

Treponema pallidum p45 recombinant antigen

Treponema pallidum TmpA recombinant

HPV L1 capsid antigen recombinant protein

Candida albicans mixed antigen

HSV2 antigen lysate

HBV HBeAg recombinant antigen

HBV Core recombinant antigen

HBV HBsAg recombinant antigen

HIV-1 antigen lysate

HIV-2 antigen lysate

HIV- 1 recombinant protein Gag

HIV-1 recombinant protein Nef

HIV- 1 recombinant protein Env.

Species d) – in utero infections: claim 142

Subspecies: Toxoplasma gondii lysate

Toxoplasma gondii Tachyzoites antigen

Rubella recombinant protein

CMV (AD 169) antigen lysate

CMV (AD 169) pp65 recombinant protein

CMV (AD169) ppl50 recombinant

CMV (AD169) pp28 recombinant protein

CMV (AD169) pp38 recombinant protein

CMV (AD169) p50 recombinant protein

CMV (C194) gB recombinant protein

HSV-1 gD recombinant protein

HSV-1 gG recombinant protein

HSV-1 viral lysate

VZV antigen lysate.

Species e) – post transplant infections: claim 143

Subspecies: CMV (AD 169) antigen lysate,

CMV (AD 169) pp65 recombinant protein

CMV (AD169) ppl50 recombinant

CMV (AD169) pp28 recombinant protein

CMV (AD169) pp38 recombinant protein

CMV (AD169) p50 recombinant protein

CMV (C194) gB recombinant protein

HSV- 1 gD recombinant protein

HSV-1 viral lysate

EBV (B95-8) antigen lysate.

Species f) – blood-borne infections: claim 144

Subspecies: HIV-1 antigen lysate

HIV-2 antigen lysate

HIV-1 recombinant protein Gag

HIV-1 recombinant protein Nef

HIV-1 recombinant protein Env

HCV Core recombinant protein

HCV p22 nucleocapsid recombinant protein

HCV NS3 recombinant protein

HCV NS4 recombinant protein

HBV HBeAg recombinant antigen

HBV Core recombinant antigen

HBV HBsAg recombinant antigen

HDV delta recombinant antigen

HGV recombinant antigen

HHV-8 antigen lysate.

Species g) – threat agent infections: claim 145.

Subspecies: Plague (Yersinia pestis) Capsular F 1 antigen

Tularemia (Francisella tularensis) LPS antigen.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner as aforementioned. The following claims are generic: claims 74-90, 97-100, 105, 106, 120, 121, 127, and 138.

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

March 26, 2010